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IN THE

Supreme Court of the United States

LABORATORY CORP. OF AMERICA HOLDINGS
Petitioner,

v.

METABOLITE LABORATORIES, INC., *et al.*
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Intellectual Property Owners Association ("IPO") is a nonprofit, national organization of about 120 large and midsize companies and more than 250 small busi-

[1] The parties have consented to the filing of this brief *amicus curiae*. The letters of consent have been filed with the Clerk of the Court. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae* or its counsel.

nesses, universities, inventors, authors, executives, and attorneys who are interested in patents, trademarks, copyrights, and other intellectual property rights. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the Patent and Trademark Office to U.S. nationals. IPO regularly represents the interests of its members before Congress and the Patent and Trademark Office ("PTO"), and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.

IPO expressly declines to take any position on whether there is a factual or legal basis for finding Respondent's patent invalid or unenforceable.

IPO's interest in this case arises from the indication that this case may be used as a vehicle for limiting the type of innovations eligible for patent protection under 35 U.S.C. § 101. IPO believes that the bounds of patentable subject matter, as delineated by the Patent Act and by *Diamond v. Diehr*, 450 U.S. 175 (1981), are both correct and clear. Any narrowing of these bounds would likely disturb the existing property rights of patentees and disrupt incentives for current and future scientific and technological research.

DISCUSSION

There are a number of provisions in the current patent laws that serve to limit the scope of patent rights granted by the Government. First, an invention must fall within the scope of the subject matter established as patentable by the Patent Act, defined as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[2] Second, the invention must have

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[2] 35 U.S.C. 101.

demonstrable specific utility,[3] be novel,[4] and constitute a non-obvious change from what was done before.[5] Third, the inventor must provide a written description of the invention sufficient to enable a person to make and use the invention, must disclose the best mode of practicing the invention, and must distinctly claim the subject matter of the invention.[6] Only in exchange for meeting all of those requirements does an inventor obtain patent rights, and then only for a limited time.[7]

Among these requirements, the scope of allowable subject matter is generally the easiest hurdle to surmount, as is warranted by the broad language of the Patent Act itself ("any new and useful process . . .") and by this Court's precedent. *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (noting that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"). There are limits on patentable subject matter, however; as the *Diehr* court recognized, "laws of nature, natural phenomena, and abstract ideas" are "[e]xcluded from such patent protection." *Id.* at 185.

The question presented for review in this case does not, on its face, challenge the current standards for patentable subject matter. However, in its invitation to the Acting Solicitor General to express the views of the United States in this case, the Court indicated an interest in considering whether the patent-in-suit claimed patentable subject matter. That inquiry required consideration of *Diehr* and the scope of patentable

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[3] *Brenner v. Manson*, 383 U.S. 519 (1966).

[4] 35 U.S.C. § 102.

[5] 35 U.S.C. § 103(a).

[6] 35 U.S.C. § 112.

[7] 35 U.S.C. § 154(a)(2) ("such grant shall be for a term . . . ending 20 years from the date on which the application for the patent was filed in the United States.").

subject matter. The Solicitor General counseled denial of the petition for writ of certiorari and endorsed the PTO's application of the *Diehr* standards to determine the scope of patentable subject matter.

IPO believes that the current standards for patentable subject matter, as set forth by the Court in *Diehr*, correctly delineate between those innovations that should be eligible for patent protection and those that should not. Accordingly, IPO believes that this case should not serve as a vehicle for overturning or altering those standards. Rather, this case should reinforce the standards of *Diehr* and thus, support the expectation that innovations in yet unknown areas of technology will be eligible for patent protection.

SUMMARY OF ARGUMENT

The standards for determining whether an innovation constitutes patentable subject matter have been correctly enumerated by this Court's precedent. The language of the Patent Act along with cases such as *Diehr* and *Chakrabarty* support patent rights in virtually every area of research or development. For several reasons, this broad scope of patentable subject matter best "promote[s] the progress" in the useful arts.

First, the broad scope of subject matter eligibility properly places research and development decision-making into the hands of individuals and private entities. The U.S. patent system is primarily an economic tool for providing incentives that promote innovation. However, by its very nature, the course of innovation is unpredictable. Through countless unexpected leaps, the state of the art in many fields of science and technology is vastly different from that of twenty-five years ago when *Diehr* was decided, and the next twenty-five years will likely continue or accelerate the rapid development of new technologies. Limiting the scope of patentable subject matter for certain areas would change this natural course of

development by attenuating the incentive to innovate. IPO believes that an open technological playing field with broad patent eligibility is the best approach in a free market system. Cases may arise where the government hopes to either encourage or discourage innovation in a particular subject matter. Those cases, however, are best left to Congress.[8]

Second, the pace and unpredictability of innovation in science and technology hinders any nuanced control over the scope of patentable subject matter. Piecemeal limitations on patent eligibility, such as a *pro forma* technologic requirement or an expansion of the "natural phenomena" exception, would simply raise further questions as the art advances. Only a broad scope of eligibility settles the law and leaves the landscape clear for maximum innovation.

Third, even without a subject matter requirement, a patent may not recapture art already in the public domain—including unrecognized natural phenomena, mathematical formulas, and laws of nature. The Patent Act provides that a patentable invention must be new, novel, and nonobvious and must be described sufficiently to enable one of ordinary skill in the art to practice the invention. Under the well-established doctrine of inherency, even a natural phenomenon, mathematical formula, or law of nature that was unknown at the time a patent application was filed may serve as prior art against the invention. The availability of these requirements as additional gatekeepers for patent rights over natural phenomena and

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[8] For over fifty years, Congress has chosen to maintain a broad scope of patentable subject matter, described as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. *See also*, Rebecca Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 Vand. L. Rev. 2081, n. 13 (2000) (noting that, in the wake of a judicial recognition of "business method" patents, Congress enacted new legislation that addressed and "arguably endorsed" the subject matter eligibility).

laws of nature further warrants against narrowing the eligibility requirements of 35 U.S.C. § 101.

ARGUMENT

I. THE COURT'S PRECEDENT ALREADY PROPERLY IDENTIFIES THE LIMITS OF PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. § 101.

In several cases, the Court has discussed the scope of patentable subject matter; IPO asserts that those decisions correctly identify the limits of patentable inventions. The existing limits efficiently promote innovation in many different fields, avoid unnecessary judicial entanglement, and allow other provisions of the Patent Act to serve as clear gatekeepers for patentability. A narrowing of the current scope of patentable subject matter would threaten all of those benefits.

Section 101 of the Patent Act identifies "Inventions patentable" and serves as the initial patentability threshold. 35 U.S.C. § 101. The "broad language" of §101 provides for the patenting of processes, machines, articles of manufacture, and compositions of matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); *Diamond v. Diehr*, 450 U.S. 175, 182-83 (1981). In *Chakrabarty*, the Court acknowledged that "Congress plainly contemplated that the patent laws be given wide scope." 447 U.S. at 308. Although the Patent Act does not have any express exclusions from statutory subject matter, the Court has recognized a list of exceptions to the scope of patentable subject matter, in particular, "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. In determining whether process claims that do not involve particular machines are patentable subject matter, transformation of an article "'to a different state or thing' is the clue to patentability." *Id.* at 184; *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).

In its brief as *amicus curiae*, the United States provided a clear outline of the rules for eligibility as patentable subject matter. *Brief of the United States as Amicus Curiae* at 5-9. In addition, the United States outlined several reasons for not using this case to alter the scope of eligibility.[9] IPO provides three further reasons why the current scope of eligibility should not be altered.

A. The broad scope of subject matter eligibility promotes a free market approach that best allocates research and development resources without judicial entanglement.

The primary underlying premise of a market economy is that relying on the market forces or "invisible hand" of supply and demand leads to greater efficiency and wealth. *See* Adam Smith, *The Wealth of Nations*, Book I (R.H. Campbell et al. eds., Clarendon Press 1976). At its core, the patent system is an economic tool that creates a strong market force—an incentive to innovate. That is, in exchange for a limited grant of exclusivity to practice his or her invention, the patentee agrees to publicly disclose that invention.

The current broad scope of subject matter eligible for patent protection allows the patent system to serve as an incentive to pursue any of a great range of potentially patentable lines of research, with each line competing for scarce resources and funding. A narrowing of patentable subject matter would cut off some of those lines and cause a reallocation of resources to other fields. The resulting system "would reduce the diversity of patentable innovation and restrict the wealth-generating potential of the patent system with artifi-

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[9] Specifically, the Government noted that (a) the record is not sufficiently developed to permit comprehensive consideration of subject matter eligibility requirements and (b) a decision narrowing eligibility requirements would undermine settled expectations and call into question a substantial number of patent claims. IPO agrees with both of these points.

cial limits on efficient market solutions." Erik Maurer, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter*, 95 Nw. U. L. Rev. 1057, 1905 (2001). An open technological playing field with broad patent eligibility is the best approach in a free market system to maximizing wealth; further narrowing patent protection to certain subject matter areas would artificially limit the incentive to innovate in those areas and thus restrict market efficiency.

Broad eligibility for patentability is vital because innovation, by its very nature, is unpredictable and leads to nonobvious results. Fifty years ago, neither software stored in computer memory nor genetically modified organisms were considered patentable subject matter. But of course, these new areas of technology had barely been conceived fifty years ago. As technology advanced, attempts to secure patents for inventions of these types met resistance in the form of a high eligible subject matter barrier. That is, then existing law led to "crises in eligibility" that regularly appeared when new forms of technology became popular. Eileen Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 Tenn. L. Rev. 707 (2004). The crises arose because the new technologies did not fit well within the then-existing standards for eligibility. For instance, *Diehr* and *Chakrabarty* were both cases involving new technology whose patent eligibility was opposed by the PTO. *Diehr*, 450 U.S. at 181; *Chakrabarty*, 447 U.S. at 306-07. Prior inventors were likely directed to other technological fields because they anticipated that they could not reap the economic benefit of innovation. Today, businesses developing technologies from the fields involved in those cases, computer-controlled operations and biotechnology, are substantial engines driving the growth of the American economy. However, their success relies heavily on protection of their intellectual property rights—rights that would not have existed under a narrower interpretation of subject matter eligibility.

The next breakthrough technology area is unknown—perhaps it has not yet been conceived. One thing is certain, however. If no patent rights are available to protect innovation in that area, investment dollars and inventors will be directed elsewhere economically. Providing an open technological playing field with full access to patent rights, regardless of the subject matter, is the best approach to ensure success in a free market system and to avoid creating disincentives against the very type of innovation that leads to landmark breakthroughs.

In some cases, there may be good reason for the government to either encourage or discourage innovation in a particular subject matter. For instance, the government may want to encourage the development of childhood vaccines or the discovery of a better method of detecting explosives hidden within luggage. Various incentives such as government grants, patent extensions, and even patent prizes have been discussed as means for stimulating research. *See, e.g.*, Michael Abramowicz, *Perfecting Patent Prizes*, 56 Vand. L. Rev. 115 (2003). All of these situations, however, are best handled by Congress and the legislative process.

B. The rapid pace and unpredictability of innovation in science and technology hinders any nuanced judicial control over the scope of patentable subject matter.

Science and technology—"the useful arts" identified in the Constitution as potential subjects for a patent system—are progressing at a blistering pace. U.S. Const., art. I, § 8, Cl. 8. Every day, hundreds of innovations, both large and small, are conceived and the downstream processes of development and patenting are begun. As entirely new areas of technology develop at an ever increasing rate, the law must remain flexible to accommodate such pace and unpredictability—making

any nuanced control over the scope of patentable subject matter difficult at best.

Piecemeal limitations on patent eligibility, such as a specific technological arts requirement or an expansion of the "natural phenomena" exception, would simply raise further questions as the art advances. Exceptions to the notion of patentable broad subject matter would likely be challenged by patentees in the PTO and in court and would create an atmosphere of uncertainty that would necessarily chill innovation.

For example, after the decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), PTO examiners were instructed to reject method claims under § 101 if the claims did not include a clear link to the "technological arts." Over time, any functional aspect of the requirement was lost and all that remained was a formalistic test that could be passed by merely reciting that a step of the questioned claim operated "through a computer." *See Ex parte Lundgren*, 76 U.S.P.Q.2d 1385 (Bd. Pat. App.& Int. 2005). In *Lundgren*, the PTO's Board of Patent Appeals and Interferences finally eliminated the technological arts test, finding "no judicially recognized separate "technological arts" test to determine patent eligible subject matter under § 101." The PTO concluded, as IPO urges here, that limiting the scope of eligibility created an artificial barrier to claiming inventions.

Similarly, numerous inventions today use newly-discovered principles. Currently, inventors can direct their research to make sure they can take economic advantage of their work. An expansion of the "natural phenomena" exception might cause such inventors to avoid disclosing the fruits of their labors or protecting them through trade secret protection. Neither of those approaches adds to the storehouse of knowledge from which others can draw to conceive further inventions. IPO believes that only a broad range of eligibility

within the scope of § 101 will settle the law in a manner beneficial to the public.

C. Strong requirements of novelty, nonobviousness, and description protect against overreaching patents and warrant against further restricting patentability based on subject matter.

One of the concerns often expressed with regard to the scope of patentable subject matter is that patents will issue that allow a monopoly on knowledge that existed independent of any invention. No one wants such overreaching or overbroad patents, and the prevention of those inappropriate patents is certainly within the purview of the Court. However, there is no cause for alarm merely because subject matter is patentable. Even without the subject matter eligibility requirements, statutory language of the Patent Act provides strong protections against attempts to obtain overreaching claims or claims directed to natural phenomena, mathematical formulas or laws of nature. Specifically, such claims must be new, nonobvious, and described sufficiently to satisfy the requirements of 35 U.S.C. § 112. As such, fears of patents directed to these areas are not well-founded and do not require any expansion of the exceptions to patentable subject matter eligibility.

It is a fundamental premise of the patent system that inventions already in the public domain may not be recaptured in a later patent application.[10] If publicly known, natural phenomena, mathematical formulas, or laws of nature would certainly serve as prior art against any patent application claiming rights thereto. Further, under the doctrine of inherency, a

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[10] Under 35 U.S.C. §102(b), a one-year grace period prevents an inventor from capitalizing on an invention for more than one year prior to filing his or her patent application.

natural phenomenon, mathematical formula, or law of nature that was unknown at the time a patent application was filed may nevertheless serve as prior art against the invention. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002). That is, the Court established over fifty years ago that natural phenomena and laws of nature are part of the "storehouse of knowledge of all men," regardless of whether those phenomena or laws were previously discovered.

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.

Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

Furthermore, an inventor must provide a written description of his or her invention. That description must enable one of ordinary skill in the art to practice the full scope of the invention, a requirement that would be difficult (if not impossible) to meet if an inventor sought to cover all uses of natural phenomena or laws of nature. By strictly enforcing all of the requirements of 35 U.S.C. § 112, the PTO can avoid any need to constrict § 101.

These requirements for patentability under 35 U.S.C. §§ 102, 103(a), and 112 further warrant against narrowing the eligibility requirements of 35 U.S.C. § 101.

CONCLUSION

IPO believes that the standards of patentable subject matter eligibility are correctly delineated by the Patent Act and *Diehr*. IPO further believes that this case should not serve as a vehicle for creating further limitations that might disrupt those standards.

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